November 7, 2017

Cook Incorporated
Colin Jacob
Regulatory Affairs Specialist
750 Daniels Way P.O. Box 489
Bloomington, Indiana 47402

Re: K173009
Trade/Device Name: NCompass Nitinol Stone Extractors
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: LQR
Dated: September 27, 2017
Received: September 27, 2017

Dear Colin Jacob:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173009

Device Name
NCompass Nitinol Stone Extractors

Indications for Use *(Describe)*
The NCompass Nitinol Stone Extractors are intended for extraction of stones or debris during biliary surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

NCompass Nitinol Stone Extractors (21 CFR §876.5010)
Date Prepared: September 27, 2017

Submitted By:

Applicant:	Cook Incorporated
Contact:	Colin Jacob
Applicant Address:	Cook Incorporated P.O. Box 489 750 Daniels Way Bloomington, IN 47402
Contact Phone Number:	(812) 335-3575 x 104965
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	NCompass Nitinol Stone Extractors
Common Name:	Dislodger, Stone, Biliary
Classification Name/Panel:	Gastroenterology/Urology
Regulation:	21 CFR § 876.5010
Regulation Name:	Biliary Catheter and Accessories
Product Code:	LQR

Predicate Device:

- Wittich Nitinol Stone Basket (K902944)

Device Description:

The NCompass Nitinol Stone Extractor is a single-use, sterile, disposable device. The extractor is a stone retrieval device consisting of nitinol basket with a 1.5 cm wide diameter when fully expanded and a 2.4 Fr shaft diameter sheath. The device is packaged with a Touhy-Borst adapter accessory.

Indications for Use:

The NCompass Nitinol Stone Extractors are intended for extraction of stones or debris during biliary surgical procedures.

Comparison to Predicate:

The NCompass Nitinol Stone Extractors and the predicate device, Wittich Nitinol Stone Basket (K902944), have the same intended use; they also share similar indications for use and principle

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of operation. The differences in technological characteristics do not raise different questions of safety and/or effectiveness when compared to the predicate device.

Substantial Equivalence Comparison

		PREDICATE DEVICE	SUBJECT DEVICE
		Wittich Nitinol Stone Basket (K902944)	**NCompass Nitinol Stone Extractor**
Regulation Number		21 CFR § 876.5010	IDENTICAL TO PREDICATE
Product Code		LQR	IDENTICAL TO PREDICATE
Classification		II	IDENTICAL TO PREDICATE
Indications for Use		For nonoperative removal of stones from the biliary tract, renal pelvis and ureter	For extraction of stones or debris during biliary surgical procedures.
One-time Use		Yes	IDENTICAL TO PREDICATE
Duration of Use		Limited (≤ 24 hours)	IDENTICAL TO PREDICATE
Principle of Operation		Basket deployment from sheath into an anatomical duct	IDENTICAL TO PREDICATE
Imaging Technique to Visualize Device		Fluoroscopy	NC3 model: IDENTICAL TO PREDICATE NCT4 model: Choledochoscope Imaging
Fluoroscopic Radiopaque Material		Tungsten/Rhenium band (located on sheath tip)	Stainless Steel (located only on NC3 basket tip)
Basket	**Tip Material**	None (tipless)	NC3 model: Stainless steel NCT4 model: None (tipless)
	Wire Material	Nitinol (nickel and titanium alloy)	IDENTICAL TO PREDICATE
	Wire Configuration	6-wire bulb shape	12-wire and 16-wire bulb shape
	Length (cm)	4.5	NC3 model: 1.9-2.3 NCT4 model: 2.1-2.5
	Outer Diameter when Deployed (cm)	2	1.5
Catheter / Sheath	**Material**	Radiopaque tetrafluoroethylene	Braided stainless steel tubing coated with Polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), and Polyimide
	Length (cm)	24	115
	Outer Diameter (Fr)	12	2.4
Additional Components		Dilator, introducer sheath	Handle, Touhy-Borst Adapter
Packaging		Polyethylene-Polyester/Tyvek	IDENTICAL TO PREDICATE
Sterilization Method		Ethylene Oxide	IDENTICAL TO PREDICATE
Sterility Assurance Level (SAL)		10^{-6}	IDENTICAL TO PREDICATE

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Technological Characteristics:

The subject devices, NCompass Nitinol Stone Extractors, were subjected to applicable testing to assure reliable design and performance under the testing parameters. The tests are listed below:

- Biocompatibility - Per ISO 10993-1, testing for cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, and material-mediated pyrogenicity were performed to ensure the biocompatibility of the subject device set. Test results indicated that all materials are biocompatible.
- Dimensional and Compatibility Evaluation (Accelerated Aged)
- Radiopacity Evaluation (Accelerated Aged)
- Multiple Stone Retrieval Testing (Zero Time)
- Tensile Test: Basket Formation (Accelerated Aged)
- Tensile Test: Basket Coil (Accelerated Aged)
- Tensile Test: Basket Sheath (Accelerated Aged)
- Tensile Test: Basket Sheath to Handle Connection (Accelerated Aged)
- Tensile Test: Basket Assembly to Shaft Connection (Accelerated Aged)
- Tensile Test: Cannula to Basket Coil Connection (Accelerated Aged)

Conclusion:

For these tests, all pre-determined acceptance criteria were met. The results of these tests show that the NCompass Nitinol Stone Extractors meet the design input requirements based on the intended use. Furthermore, these results support the conclusion that the NCompass Nitinol Stone Extractors do not raise new questions of safety or effectiveness and support a determination of substantial equivalence.